UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,846	10/10/2003	William Richard Heineman	0091830/0517360	2736

26874 7590 06/14/2006

FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

EXAMINER
DIRAMIO, JACQUELINE A

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/683,846	**Applicant(s)** HEINEMAN ET AL.	
	Examiner Jacqueline DiRamio	**Art Unit** 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/17/05*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The amendments to claims 1, 3, 7, 8, and 12 are acknowledged.

Currently, claims 1 – 22 are pending, however, claims 13 – 22 have been withdrawn as drawn to a non-elected invention.

Withdrawn Objections and Rejections

The previous objection to the specification is withdrawn in light of Applicant's amendment filed April 4, 2006.

All previous rejections have been withdrawn in view of Applicant's arguments and amendments filed April 4, 2006.

Response to Arguments

Applicant's arguments, see p8-12, filed April 4, 2006, with respect to the rejection(s) of claim(s) under 35 U.S.C. 102 have been fully considered and are persuasive. The first 102 rejection, which cited the Pyle et al. reference (US 5,821,066), does in fact only teach potable water, which as defined by Applicant, differs from the "finished water" taught by the instant application, and therefore, Pyle et al. do not anticipate Applicant's claim 1. However, Pyle et al. do include the step of "determining the effect the (potable) water has on the targeted agent," wherein the water sample of Pyle et al. is initially collected and dyed with a fluorochrome dye in order to determine if there are viable or respiring cells (see cl.1). Therefore, the broad "determining" step of the instant application is taught through this step of Pyle et al. because it is first determined if there are live target cells in the potable water, which can be considered an "effect" of the potable water, before performing the subsequent detection steps.

The second 102 rejection, which cited the Fritsch et al. reference (US 2003/0108922), does apply a method of detection to finished water, however the step of "determining the effect said finished water has on the targeted agent," is not distinctly taught by the Fritsch et al. reference, and therefore, Fritsch et al. also do not anticipate Applicant's claim 1.

Therefore, the previous rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyle et al (US 5,821,066) in view of Fritsch et al. (US 2003/0108922).

Pyle et al. teach a simple, rapid method for detection of specific microorganisms, particularly in potable water sources and water storage areas (see column 6, lines 48-53). The method comprises the steps of:

analyzing a sample for a particular target species in food or water;

determining if the target species is viable in the food or water sample, by collecting the sample and dyeing with a fluorochrome dye in order to determine the presence of any viable target cells;

selecting and providing an antibody (first molecular recognition element) that specifically binds to a particular species of target bacteria in the sample of water;

mixing (flowing) the liquid (sample) suspected to contain the target bacteria with the specific antibody (first recognition element);

capturing the bacteria (biological agent) present in the sample with the specific antibody (first recognition element) through binding;

emitting a fluorescence signal, which indicates the presence of the target bacteria in the sample (see column 7, lines 17-36; example 3, columns 17-18, and claim 1 in particular).

However, Pyle et al., which teach the method of detecting in potable water sources, fail to teach that the method also encompasses “finished water” samples.

Fritsch et al. teach an electrochemical detection method for pathogens and toxins in water supplies, particularly finished water. The method of Fritsch et al. comprises:

analyzing a sample suspected of having a target analyte (biological agent);

selecting and providing a primary analyte binding material (first molecular recognition element), which targets the biological agent in the sample;

introducing (flowing) the sample to be tested for a specific analyte to the assay structure, which contains the primary analyte binding material (first molecular recognition element);

capturing the biological analyte in the sample through binding to the primary analyte binding material (first molecular recognition element); and

creating a current (emitting a signal) within the assay structure via a electrochemically active material, which indicates the presence of the analyte in the sample (see paragraphs [0024], [0025], [0027], [0036] and [0038] in particular). By detecting the concentration of target analytes, such as toxins and pathogens, in finished water samples, the possibility of an outbreak occurring in the finished water supplies can be reduced, which provides for cleaner, safer drinking water and will reduce fatality rates worldwide (see paragraphs [0027] and [0058]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the detection method of Pyle et al. the use of finished water samples as taught by Fritsch et al. because Fritsch et al. teach the benefit of detecting pathogens in finished water samples in order to reduce the possibility of an outbreak occurring in the finished water supplies, which provides for cleaner, safer drinking water and will reduce fatality rates worldwide.

With respect to Applicant's claims 2 – 4, Pyle et al. teach that the bacteria that has been captured by binding with the specific antibody is next treated with a specific fluorescent conjugated antibody (second molecular recognition element) that also binds to the captured bacteria (see column 18, lines 2-10 in particular). The fluorescent label provides the emitted fluorescence signal to indicate the presence of the target bacteria in the sample, wherein the signal is quantifiable using an image analysis system (see column 18, lines 30-42 in particular).

With respect to Applicant's claim 5, Pyle et al. fail to teach the use of electrochemical detection, however, the method of Fritsch et al. utilizes electrochemical detection, wherein the signal emission generated through a created current is detected electrochemically (see paragraphs [0024] and [0025]). Fritsch et al. teach that their detection method can use fluorescence techniques, however, the methods of electrochemical detection provide a more accurate and less time intensive detection method (see paragraph [0049]). Therefore, it would have been obvious to include the electrochemical detection method with the method of Pyle et al. because Fritsch et al. teach the benefit of this detection method in order to provide a more accurate and less time intensive detection method.

With respect to Applicant's claim 6, Pyle et al. teach that the signal emission is capable of fluorescence detection, as discussed above (see column 18, lines 1-42).

With respect to Applicant's claim 7, the element used by Pyle et al. to specifically bind to the target bacteria is an antibody (see column 17, lines 53-58 in particular).

With respect to Applicant's claims 8 and 9, Fritsch et al. teach the sample is treated with an electrochemically active material, which contains an electrolabeling material and either a metal ion, a redox enzyme, a metalloprotein, or a chelating agent. The electrochemically active material is added along with the secondary analyte binding material (second molecular recognition element) to bind to the target agent and create the electrochemical signal, without interfering with the primary analyte binding material (first molecular recognition element) (see Figure 1, paragraph [0063], and claim 2 in particular).

With respect to Applicant's claim 10, Pyle et al. teach the biological agents detected by the method of Pyle et al. mainly consist of pathogenic bacteria (see column 16, lines 54-56 and column 17, lines 53-56 in particular).

With respect to Applicant's claims 11 and 12, Pyle et al. teach the antibody (first molecular recognition element) used to specifically bind to the target bacteria is coated on a solid phase, particularly immunomagnetic beads (see column 17, lines 53-58 and column 18, lines 55-60).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jackie DL

Jackie DiRamio
Patent Examiner
Art Unit 1641

LONG V. LE 06/09/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600